



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION UNDER RULE 131

Applicant: Roger P. Jackson

Serial No.: 09/644,777

Date: February 25, 2003

Filed: August 23, 2000

Group Art Unit: 3732

Exam: Candice Melson

For: THREADFORM FOR MEDICAL IMPLANT CLOSURE

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Kansas City, Missouri

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicant, Roger P. Jackson, in the above captioned application for patent avers and declares as follows:

- 1) I am the inventor of the subject matter of the claims of U.S. application for patent Serial No. 09/644,777.
- 2) I am a spinal surgeon. In the late 1980's and early 1990's and especially in 1992 and 1993 I worked on developing a spinal implant system at my office in North Kansas City, Missouri which eventually became the

Liberty System of Sofamor, later Sofamor Danek, Sofamor Danek Group Incorporated, and SDGI Holdings, Inc.

- 3) During 1992 and 1993 I provided office space in my medical practice office to several engineers from Sofamor who worked as an interface between myself and Sofamor with respect to the development work I was doing. In particular, beginning in October 1992 Jean Saurat, an employee of Sofamor began work in my office and in April 1993 Paul Wisnewski, an engineer employed by Sofamor began work in my office and overlapped with Mr. Saurat.

- 4) Also especially from 1991 to 1993 (and in some cases earlier) I developed certain other inventions and concepts outside the realm of the Liberty Spinal System and disclosed these inventions and concepts to Sofamor and especially to the Sofamor engineers who were working with me on the Liberty System. I also disclosed these concepts to Dr. Hardacker in the Fall of 1992 who was a spine fellow then training in my office to practice spinal surgery.

- 5) Enclosed as Exhibit A is a drawing of a concept that I made of two closure plugs, one with a standard V thread and one with a reverse angle or buttress thread. The drawing of Exhibit A was made during a trip to Heidleberg, Germany from which I returned on May 17, 1991. The file for this drawing was created immediately upon return from this trip. During 1992 and 1993 I maintained a bound log and files on various inventions and concepts that I developed. Exhibit B is a drawing that is located in my 1992 file and was done by me in mid 1992. The bottom design in Exhibit B illustrates a reverse angle thread on a closure mechanism in accordance with my invention in the present application.
- 6) Enclosed as Exhibit C is a drawing from my bound log that was made by me and that is dated December 2, 1995. The top illustration of Exhibit C illustrates a closure plug having a reverse angle thread as disclosed and claimed in my application for patent.
- 7) The closure mechanism with the buttress and reverse angle threads that is shown in Exhibits A and B was

shared with, shown to and extensively discussed with the Jean Saurat from Sofamor and Dr. Hardacker during the period from 1992 to 1993. A letter from Dr. Hardacker dated March 19, 2001 confirms disclosure of information to him at that time and is included as Exhibit D. Dr. Hardacker was specifically shown Exhibit B and remembers this disclosure as having been shown to him and discussed in 1992. The Sofamor personnel indicated that Sofamor was not interested in the idea because Sofamor felt it was an impractical approach and they wanted to pursue a different avenue to prevent splaying of the arms of bone screw heads.

- 8) I attempted to have the device of Exhibit A constructed by Jenkins Industrial Machine Works in North Kansas City, Missouri at least as early as 1995. Jenkins is a machine shop that I use to produce many of my prototypes. The personnel at Jenkins indicated that they did not have the technology to produce the reverse angle thread on a bone screw closure mechanism at that time. The personnel at Jenkins also indicated that they had checked to see if the technology was available anywhere, but could not find the technology to build

the closure with the reverse angle thread. The personnel at Jenkins indicated that I would have to wait until the technology existed to make a prototype.

- 9) I never lost interest in the concept of using the reverse angle thread on a bone screw closure and continued to pursue making and testing a prototype.
- 10) Finally, in 1999 after much prodding, the personnel at Jenkins informed me that the technology was available to undercut the threads and manufacture a reverse angle thread on the closure mechanism. At that time, I had prototypes made and began testing the prototype. Exhibit E is a billing from Jenkins dated September 15, 1999 for the work in making a prototype. Exhibit F is another drawing of mine from my log dated March 31, 1999 showing the reverse angle thread on a closure on the left. Exhibit G is a drawing of mine dated December 2, 1995, a copy of which is located in the Jenkins files in a folder marked "Dr. Jackson". Exhibit H is another drawing from the Jackson file at Jenkins showing the reverse angle thread on a closure plug that was done by Jenkins prior to October 13, 1999

and which was labeled "Buttress" thread, as the term reverse angle thread was not in common use at that time. Exhibit I is a bill for stock used to produce a closure with a reverse angle thread from titanium stock for me that is dated October 13, 1999. Exhibits J, K and L are photographs of prototypes of the closure with the reverse angle thread made in September or October 1999. Note the device in Exhibit K has been sliced to show the cross section.

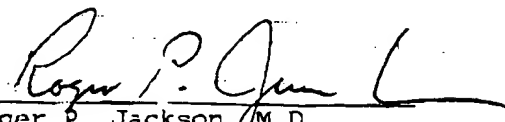
- 11) The prototypes of the closure with reverse angle threads with my invention were made by Jenkins and tested in the North Kansas City, Missouri area beginning in September and October 1999. The drawings for the present application were made from some of the first prototypes produced.
- 12) The Morrison patent 6,296,642 is assigned to SDGI Holdings, Inc. which is the holding company that owns the patents for the prior noted Sofamor company to which I disclosed my invention that is the subject matter of this application during 1992 and 1993.

13) I believe that I was the first to conceive of the idea of using a reverse angle thread on a closure plug or mechanism for an open headed bone screw, as described and claimed in my application for patent. I also believe that I reduced the concept to practice in the United States with due diligence from my date of conception in view of the slow development of the machining technology that was available to construct such a device. As the technology developed, I proceeded with the project and never lost or abandoned interest in the closure for a bone screw with the reverse angle thread. I also believe that I disclosed this invention to Sofamor which now claims to have invented the invention through its employees Morrison, et al.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may

jeopardize the validity of the application or any patent issued thereon.

Respectfully Submitted,


Roger P. Jackson, M.D.

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231 on February 25, 2003.

Roger P. Jackson
(Applicant)

By



February 26, 2003

(Date of Signature)